EXHIBIT 5

: ::ODMA\MHODMA\iManage;302735;1 JMS/jat PATENT APPLICATION Attorney's Docket No.: 1159.1006-007

O. Sauce

SF 0.3 2002

August 27, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

licants: Steven A. Bogen, Herbert H. Loeffler and John A. Purbrick

Application No.: 09/688,619

Group:

1743

Filed:

October 16, 2000

Examiner:

J. Snay

For: Random Access Slide Stainer with Independent Slide Heating Regulation

DO NOT BATE

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202 on 8/27 / OZ Date. Signature

Typed or printed name of person signing certificate

AMENDMENT

Assistant Commissioner for Patents P.O. Box 2327 Arlington, VA 22202

Sir:

This Amendment is being filed along with a Request for Continued Examination in response to the Office Action mailed from the U.S. Patent and Trademark Office on March 27, 2002 in the above-identified application. Reconsideration and further examination are requested.

An extension of time to respond to the Office Action is respectfully requested. A Petition for Extension of Time and the appropriate fee are being filed concurrently with this Amendment.

Please amend the application as follows:

-2-

In the Claims

Please amend Claims 1, 2, 3 and 5. Amendments to the claims are indicated in the attached "Marked Up Version of Amendments" (pages i - ii).

1. (Twice Amended) A method of processing samples mounted on microscope slides comprising:

placing two or more microscope slides on a moving platform, the moving platform having heating elements thereon to heat said slides;

communicating data from a computer not located on the moving platform to electronic circuitry mounted on the moving platform; and

processing the data in the electronic circuitry on the moving platform and supplying, from the electronic circuitry on the moving platform, amounts of electrical power to the heating elements dependent on the data, to heat one of the slides to a different temperature than a second one of the slides.

(Amended) A method of processing samples mounted on microscope slides as claimed in claim 1, wherein each heating elements heats only one slide.

(Amended) A method of processing biologic samples mounted on microscope slides as claimed in claim 1, wherein the moving platform is capable of indexing slides adjacent to a stationary liquid dispensing location.

(Amended) A method of processing samples mounted on microscope slides comprising, positioning a plurality of microscope slides bearing biologic samples on a moving platform, said moving platform having a plurality of heating elements controllable to individual temperatures and electronic circuitry thereon;

providing a computer comprising a user interface through which a desired temperature for each microscope slide is specified, said user interface being mounted off of the moving platform;

A

0 (7) 1_{2.}

Z

3) 5.

8



-3-

sending data from the computer to the electronic circuitry on the moving platform over a group of conductors, the number of conductors in said group of conductors being less than the number of heating elements controllable to individual temperatures; and

processing the data in the electronic circuitry on the moving platform, and supplying electrical power to the heating elements from the electronic circuitry on the moving platform.

Please add new Claims 6, 7, 8 and 9.

6.

(New) A method of processing samples mounted on microscope slides comprising: placing two or more microscope slides on a moving platform;

providing heating elements capable of heating said slides, said heating elements being under independent electronic control and thereby capable of heating some slides to a different temperature than other slides; and

on the moving platform, heating one slide to a different temperature than a second slide.

(New) A method of processing samples mounted on microscope slides as claimed in claim b, wherein each heating element heats only one slide.

(New) A method of processing samples mounted on microscope slides as claimed in claim 6, wherein the moving platform is capable of indexing slides adjacent to a stationary liquid dispensing location.

(New) A method of processing samples mounted on microscope slides as claimed in claim 6, wherein said heating elements are mounted on said moving platform.

REMARKS

Claims 2 and 3 have been amended to make them consistent with base claim 1 and thus overcome the rejection under 35 U.S.C. 112.

The examiner requested further description of the actual implementation of the prior Bogen et al. system. That description can actually be found in the present application in the description of figure 7 at the paragraphs bridging pages 7 and 8 and pages 15 and 16. Note in figure 7 that the temperature controller 21 is stationary on the base of the system and the conductors 22, 23 to the plural heating elements are included in a service loop. However, the undersigned did not intend to suggest that the prior implementation was prior art. That implementation was included in an early prototype but was never publicly disclosed, in public use or offered for sale. The original claim 1 covered that implementation and applicant is resubmitting that claim as new claim 6. Claims 1-5 were only limited by amendment to the improved implementation to expedite prosecution.

New claims 6 through 9 correspond to the originally filed claims 1 through 4, amended to overcome the rejections under 35 U.S.C. 112 presented in the last office action.

Claims 1-3 and 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bogen et al. ('114) in view of Muller et al. ('905) or Potter et al. ('842) and further in view of Home ('299). That rejection is respectfully traversed, and reconsideration is requested.

The present invention is a method for processing samples mounted on microscope slides. A prime task in such methods is the handling of fluids which are applied to and extracted from each slide through some predetermined sequence. For example, washing fluids may be applied to the sample and extracted, and thereafter a selected reagent may be applied.

Muller et al., is illustrative of one class of slide processing system. As illustrated in Fig. 5, a slide 41 is positioned in a fixed assembly to form one wall of a narrow chamber 46. As

09/688.619

-5-

illustrated in Fig. 20, a number of reservoirs R1 through R11 and a cooling water supply 117 are connected through fluid lines to a slide specimen chamber 112. Muller et al. also provides for both electrical and fluid temperature regulation of the stationary slide supporting block (column 18, lines 26-30).

The plumbed lines from the fluid reservoirs of Muller et al. are not suitable for expensive reagent which must be supplied in very small amounts. The void volume for such permanently plumbed lines is much too high, and there would be the problem of cross contamination because the same lines would have to be used for different staining procedures. Thus, the plumbed lines of Muller et al. are only satisfactory for bulk liquids such as buffers. To address that shortcoming, Muller et al. allows for the use of a hyperdermic needle to inject fluid into the chamber 46 through a channel 91. (See column 5, lines 43-50 and column 19, lines 7-39.)

Because of the need for a manual syringe to apply microvolumes of a reagent, Muller et al. is not suitable for fully automated, walkaway processing of samples and slides. One solution, of course, has been to use robotics to move syringe elements into place. However, such systems are complex. Another class of microscope slide processing systems is represented by Bogen et al. and, for example, the previously cited Healy et al. (5,425,918) and Copeland et al. (5,595,707) patents. In such a system, the microscope slides are positioned on a carousel which allows individual slides to be moved into position below a dispensing station from which a microvolume of a reagent may be applied. Other stations allow for washing with bulk solutions, extraction of fluids and the like. It is to such systems, which allow for convenient microvolume fluidic handling, to which the present invention is directed.

To date, systems in which the microscope slides are placed on a moving platform have not provided for individual heating of those slides. For example, the Copeland et al. system has a convection heating station into which a portion of the carousel is moved. The Bogen et al., system provides hot plates on the carousel on which the slides are supported. However, as the Examiner has noted, Bogen et al. fails "to recite each of the heating elements having the

-6-

capability of heating to different temperatures." The only discussion of the heaters in Bogen et al. is presented at column 5, lines 49-58 and column 8, lines 9-11.

Muller et al. has been cited for a teaching of heating elements capable of heating to different temperatures. However, as discussed above, Muller et al. relates to a system having stationary sample chambers with permanently plumbed fluid and electrical connections to the stationary chambers. The closed, sealed, stationary chambers of Muller et al. are incompatible with and teach away from the open, rotary carousel approach of Bogen et al., and the permanently plumbed lines to each slide are incompatible with and teach away from the moving, rotary carousel of Bogen et al. Having rejected the fixed station approach of Muller et al. in favor of the more flexible fluid handling of slides positioned on a moving platform, one would not look back to Muller et al. for a teaching of how to handle the samples on the moving platform.

Potter et al., like Muller et al., merely discloses a stationary, heated slide support, and teaches no more than Muller et al.

Thus, there is no suggestion in the prior art of heating individual slides to different temperatures where those slides are mounted on a moving platform as required by each of the pending claims.

Even once Applicants considered the individual temperature control of slides on the moving platform using the heat plates of Bogen et al., the final solution recited in claims 1-5 was not obvious. The initial implementation relied on individual wires from the base microprocessor to the individual heating elements to provide for the individual control. Although that approach was adequate for a small number of heating elements, with a substantial number of heating elements, the large number of electrical conductors became cumbersome. As a solution to that problem, applicants provided processing electronics on the moving platform to control the power to the individual heaters while limiting the electrical conductors between the base microprocessor

-7-

and the moving electronics to a single set of power lines and communication lines to be shared by all heating elements.

Thus, not only is it not suggested in the prior art that individual temperature control be provided to slides on a moving platform, but there is no suggestion of mounting the electronic circuitry on the moving platform to facilitate the individual control as recited in claims 1-5.

The Examiner has acknowledged that the combination of Bogen et al. with Muller et al. and Potter et al. "fails to specify the temperature control being effected by communicating data from a computer located off the moving platform to a electronic circuitry located on the platform." In that respect, Horne has been cited. However, Horne is not of the class of systems in which microscope slides are mounted on a moving platform. Horne does not process microscope slides, and as illustrated in Figure 2, sample carrying cartridges 22 are positioned in fixed slots 20 and are heated by stationary heaters 40. See column 7, lines 14-28. Accordingly, relative to the claimed invention, Horne at most repeats the teachings of Muller et al. In looking at either Muller et al. or Horne, one would see stationary heaters and would thus not look for a solution to the problem of Bogen et al. of heating samples on microscope slides located on a moving platform. In fact, Horne teaches away from the present invention in teaching stationary heaters.

The communication link of Horne to which the Examiner refers at column 11, lines 40 et seq. relate to communications with optical components. There is no suggestion in either of the references of using such a communication link to drive the electrical load of heating elements. In fact, as already noted, Horne teaches away from such a combination since Horne teaches that samples and their heaters should be stationary.

The examiner further suggests that the wires and conductive heaters in Bogen et al. would have constituted "circuitry within the scope of the presently claimed term." First, it is noted that "heating elements" are separately recited in the claims, so those elements can not be considered a part of the separately recited electronic circuitry. Further, mere conductors can not be considered

electronic circuitry, a term which implies processing of the received data. That limitation is explicitly recited in the above amended claims.

With respect to claim 5, the examiner notes that Bogen et al. discloses "a number of conductors which is less than the number of heating elements in figure 6 and 7." In Bogen et al., the heating elements on a common slide frame are driven with a common current to serve as a single temperature heater. The number of wires to the slide frame is not less than the number of heating elements controllable to individual temperatures. That distinction is now explicitly recited in amended claim 5.

The parent to this application, patent 6,183,693, is the subject of litigation. A copy of the Defendant's Answer to First Amended Complaint and Counterclaims is attached. The Defendant has presented no evidence to support the allegations of invalidity.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

James M. Smith, Esq.

Registration No. 28,043 Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133 Dated: 8/27/2